



EU Declaration of Conformity according to the PPE regulation (EU) 2016/ 425

The manufacturer:

EFA SOLUTION sh.p.k.

Rr. Gjergj Balshaj, 6

Tirana

Albania

Declares on its own responsibility that

Article

201397 Isolation gown (PP with PE coating)

Is conform to Regulation (EU) 2016/ 425 and complies with the harmonized standards:

EN ISO 14126:2004	EN ISO 13688:2013
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This product is PPE of category III according to Annex I of the Regulation and is identical to the PPE covered by the EU Type Examination Certificate No. CE 1396210027-00-00 issued by Centrocot (identification number 0624)

and is subject to the procedure according to module C2 of Regulation (EU) 2016/ 425 under the control of the notified body Centrocot (identification number 0624).

Technical documentation meeting the requirements is available as proof.

Tirana, 20.01.2021

Etleva Laro

CEO



This declaration of conformity is valid until 20.01.2026

Efa Solution sh.p.k. NUIS L51527001P Address: Rr. Gjergj Balshaj, 6 Tirana, Albania	Mob. +355 69 6071313 Tel. +355 45 62 00 30 info@efasolution.al www.efasolution.al	EFA Solution sh.p.k. Procredit Bank Albania AL17209110810000080768020102 SWIFT CODE: FEFAALTR
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CERTIFICATE

N. AL20-36512H

This is to certify that the Quality Management System for Medical Devices of

EFA Solution Sh.p.k.

VAT Registration no.: L51527001P

Address: Rruga "Gjergj Balshaj", Godina Nr. 6, Tirana, Albania

HAS BEEN INDEPENDENTLY ASSESSED AND FOUND IN CONFORMANCE WITH THE STANDARD

ISO 13485:2016

FOR THE FOLLOWING SCOPE OF ACTIVITIES:

Manufacture and distribution of non-sterile gowns for medical use.

Category A.1.1

For further and updated information regarding any changes in the status of this certification please contact via phone under +35544509900 / +390296368458 or via email to info@axe-register.com.

The validity of this certificate is subject to periodic yearly surveillance audit and triennial review of the entire management system of the certified organization.

Date of initial registration

17/02/2021

Date of this certificate

17/02/2021

Certificate expiration

16/02/2024

On behalf of the Certification Body

AXE REGISTER

Antonio Llavda

Technical Director



CS 007



CERTIFICATE

N. AL20-29607H

This is to certify that the Quality Management System for Medical Devices of

ProDyn Albania sh.p.k.

VAT Registration no.: L62120003K

Address: Rruga "Gjergj Balshaj", Godina Nr.6, Tirana, Albania

HAS BEEN INDEPENDENTLY ASSESSED AND FOUND IN CONFORMANCE WITH THE STANDARD

ISO 13485:2016

FOR THE FOLLOWING SCOPE OF ACTIVITIES:

Manufacture and distribution of non-sterile gowns for medical use.

Category A.1.1

For further and updated information regarding any changes in the status of this certification please contact via phone under +35544509900 / +390296368458 or via email to info@axe-register.com.

The validity of this certificate is subject to periodic yearly surveillance audit and triennial review of the entire management system of the certified organization.

Date of initial registration	17/12/2020
Date of this certificate	17/12/2020
Certificate expiration	16/12/2023

On behalf of the Certification Body

AXE REGISTER

Antonio Llavda
Technical Director



CS 007



This document is issued
based on Certification
System of EQSC and the
relevant Standard.

The validity of this
certificate maintained
through annual surveillance
audits and re-certification
audit (every three years).

EQSC reserves the right to
withdraw this certificate
under the conditions laid
down in its System
Certification.

Accredited by



CS 004 24.11.2014
CS 010 04.12.2018

CERTIFICATE

European Quality and Safety Control (EQSC)

issues this certificate to

ProDyn sh.p.k
Rr. Gjergj Balshaj, Godina nr. 9,
1001 Tirana, Albania

prodyn

Confirming the development and effective implementation of
QUALITY MANAGEMENT SYSTEM

In accordance with Requirements of International Standard:
ISO 9001:2015

Scope of Activity:

Manufacture of leather footwear, bags, car accessories and other leather related products.
Manufacture of personal protective equipment, textile bags and related accessories.
Trade of leather and textile products.

EA: 29

Certificate number: 0150
Initial Certification Date: 16/11/2018
Date of issue: 29/06/2020
Valid until: 15/11/2021
Revision number: 01

This document is issued
based on Certification
System of EQSC and the
relevant Standard.

The validity of this
certificate maintained
through annual surveillance
audits and re-certification
audit (every three years).

EQSC reserves the right to
withdraw this certificate
under the conditions laid
down in its System
Certification.

Accredited by



CS 004 24.11.2014
CS 010 04.12.2018

CERTIFICATE

European Quality and Safety Control (EQSC)

issues this certificate to

ProDyn sh.p.k
Rr. Gjergj Balshaj, Godina nr. 9,
1001 Tirana, Albania

prodyn

Confirming the development and effective implementation of
**OCCUPATIONAL HEALTH AND SAFETY
MANAGEMENT SYSTEM**

In accordance with Requirements of International Standard:
ISO 45001:2018

Scope of Activity:

Manufacture of leather footwear, bags, car accessories and other leather related products.
Manufacture of personal protective equipment, textile bags and related accessories.
Trade of leather and textile products.

EA: 29

Certificate number: 0238
Initial Certification Date: 16/11/2018
Date of issue: 29/06/2020
Valid until: 15/11/2021
Revision number: N/A

EQSC
European Quality & Safety Control